

Application Serial No. 10/780,904
Response to Official Action of September 3, 2004
Dated: December 3, 2004

REMARKS/ARGUMENTS

This paper is filed in response to the Official Action mailed September 3, 2004 for the above-captioned application. Reconsideration of the application, as amended, in view of the remarks herein is respectfully requested.

The Examiner objected to claim 20 as having a semi-colon rather than a comma after "claim 19". In Applicants' copy, there is a comma, although there may also be a flaw in the paper which may have been copied. No amendment is made to claim 20, but the claim is now clearly presented with a comma.

Claim 22 was objected to under 37 CFR 1.75(c) as failing to limit the claim from which it depends. The Examiner states that because the first antibody pair as recited in claim 21 is directed against both the alpha and beta peptide chains of FSH, it necessarily detects total FSH such that claim 22 does not further limit the claim. The Examiner appears to be arguing that something that binds to both chains cannot also be an antibody that differentiates between isoforms of FSH. There is no factual basis for this. In fact, the application shows two specific antibodies, both of which were induced against the combination of alpha and beta chains, which have different binding specificity. This being the case, Applicants respectfully submit that the claim 22 does properly limit claim 21, and that the objection should be withdrawn.

Claim 31 has been amended to be dependent on claim 18. This overcomes the objection to claims 31 and 32.

Claim 33 has been amended to correct the grammatical errors noted by the Examiner (although the Examiner indicated errors in claims 33 and 34, which both appear to be in claim 33).

The Examiner rejected claims 21, 23-25, 29, and 31-32 under 35 USC § 112, second paragraph as indefinite. Applicants have amended the claims or traverse the rejections for the reasons set forth below.

With respect to claims 21-25, the Examiner says that these claims are indefinite because two antibodies directed to the alpha and beta peptide chains of FSH would measure the same thing, while claim 18 requires that the two antibodies have different specificity. Although the Examiner has not clearly stated her position, it appears from the quotation marks around "peptide chains" on page 3, that the Examiner is interpreting this phrase to mean just the peptides and not other potential modifications. This is not what was intended, and claim 21 has been amended to refer to "combined alpha and beta chains of FSH." This amendment should overcome the

Application Serial No. 10/780,904
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rejection to the extent it was understood by Applicants. Further, this amendment addresses the rejection of claim 23, which was also based on the assumption that the two measured values would be the same.

Claim 24 has been amended to make it expressly clear that the repeat testing is done on a new sample obtained from the same individual after the passage of a least one week and then performing the assays on this second sample. This amendment should overcome the rejection as understood from the examiner's remarks. Claim 29 has been amended in the same manner, although the rejection of claim 29 was phrased entirely differently from the rejection of a text identical (except for the claim referred to) claim 24.

In view of these amendment and arguments, the rejection under 35 USC § 112, second paragraph should be withdrawn.

Claims 18-20 and 33-37 stand rejected under 35 USC § 102 as anticipated by US Patent No. 5,391,272 of O'Daly et al. In order for there to be anticipation, the reference cited by the Examiner must disclose each and every element of the claimed invention. By the Examiner's own characterization, this standard is not met by O'Daly.

Claim 18 recites the following steps:

(a) obtaining a gonadotropin-containing sample from the human female individual, wherein **the gonadotropin** present in the sample exists in a plurality of different forms, and wherein the form or forms in which **the gonadotropin** exists differ depending on whether or not the human female individual is pre-menopausal or post-menopausal;

(b) performing contemporaneous first and second assays on the sample obtained in step (a),
said first assay producing an indication of **the gonadotropin** that is independent of the whether the individual is pre-menopausal or post-menopausal, and said second assay producing an indication of **the gonadotropin**, ...

By ordinary usage, and by ordinary rules of patent claim construction, the term "the gonadotropin" refers to the same thing throughout the claims. Thus, the gonadotropin which is the subject of the first assay is the same gonadotropin which is the subject of the second assay, and it is the gonadotropin that exists in a plurality of different forms. By the Examiner's own statement, O'Daly's two assays are for different gonadotropins, namely FSH and LH.

Application Serial No. 10/780,904
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Furthermore, the reference is completely silent with respect to determination of menopausal status. Thus, there can be no anticipation, and this rejection should be withdrawn.

The Examiner also rejected claims 18-20 and 26-29 under 35 USC § 102 as anticipated by Overlie et al. (1999). This rejection suffers from the same defect as the O'Daly rejection. The tests in Overlie are for a variety of different gonadotropins, but there is no instance in which a pair of tests for the same gonadotropin are performed. Further, the ration referenced by the Examiner is FSH/LH, not FSH1/FSH2, which is what would be required in the claimed invention in the case where the gonadotropin were FSH.

The Examiner rejected claims 18 and 26-30 under 35 USC § 102 as anticipated by US Patent No. 6,521,416. Again, the Examiner has ignored the language the claims and considered listing of a collection of different and unassociated assays as a disclosure of a specific usage of a assay pairs for the same gonadotropin. The reference does not support such a conclusion and the rejection should be withdrawn.

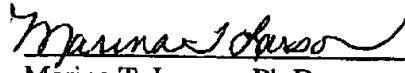
The Examiner rejected claims 18 and 26-27 as anticipated by Niccoli et al. (1996) as evidenced by Costagliola et al. (1194) Again, the reference simply provides a collection of unassociated assay, and does not provide any methodology for using these assays in combination as claimed for determination of menopausal status. Further, it is noted that assay I, which the Examiner identifies as a first assay in accordance with the invention is noticeably not independent of the menopausal state of the woman being tested. The Examiner is not permitted to ignore the words of the claims when formulating an anticipation rejection. This rejection should be withdrawn.

It is further noted that the Examiner has cited art that is not relied upon. In the body of this discussion, there are allegations that these references "disclose the invention of claims 33 and 37) or "disclose the instantly claimed invention." If it is the Examiner's belief that these references in fact are of relevance to the claimed invention, properly construed, then they should be cited in a rejection not left in an uncertain limbo at the end of the Office Action. If no such rejection is made, Applicants respectfully request that the Examiner, having raised the issue, expressly state that these references are also not a bar to patentability of the present claims.

Application Serial No. 10/780,904
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Applicants note that claims 15 and 16 were indicated to be allowable in the parent case. In view of this and the arguments made herein, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,



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